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CV'08 - 6363

# UNITED STATES DISTRICT COURT DISTRICT OF OREGON

SCOTT WARNER; ERIN STOUT and RUSSELL STOUT, wife and husband; THOMAS BOBRICK and BARBARA BOBRICK, husband and wife; BRIAN CANTRELL; JAMES EVANS; WELDON SMITH and KELLIE SMITH, husband and wife; CHRIS TRANOS and COURTNEY TRANOS, husband and wife; GEORGE LIMANTZAKIS; RICHARD STEFFENS and NADINE STEFFENS, husband and wife; CHRIS ZAVARELLA and STACEY ZAVARELLA, husband and wife.

08-CV-	

COMPLAINT Personal Injury Action (28 U.S.C. § 1332) DEMAND FOR JURY TRIAL

PLAINTIFFS.

17341.001/4842-6438-3491.7 # 2787

VS.

STRYKER CORPORATION, a Michigan corporation; STRYKER SALES CORPORATION, a Michigan corporation; I-FLOW CORPORATION, a Delaware corporation; DJO, LLC (f.k.a. DJ ORTHOPEDICS, LLC), a Delaware limited liability company; DJO, INC., a Delaware corporation; BREG, INC., a Delaware corporation; ORTHOFIX, INC., a Minnesota corporation; ASTRAZENECA, PLC, a United Kingdom corporation; ASTRAZENECA PHARMACEUTICALS LP, a Delaware limited partnership; ASTRAZENECA LP, a Delaware limited partnership; ZENECA HOLDINGS, INC., a Delaware corporation; HOSPIRA, INC., a Delaware corporation; and ABRAXIS BIOSCIENCE, INC. (f.k.a. NEW ABRAXIS, INC., f.k.a. AMERICAN PHARMACEUTICAL PARTNERS, INC., a.k.a. APP REINCORPORATION COMPANY, INC, a.k.a. APP PHARMACEUTICALS INC.),

DEFENDANTS.

COME NOW Plaintiffs SCOTT WARNER; ERIN STOUT and RUSSELL STOUT, wife and husband; THOMAS BOBRICK and BARBARA BOBRICK, husband and wife; BRIAN CANTRELL; JAMES EVANS; WELDON SMITH and KELLIE SMITH, husband and wife; CHRIS TRANOS and COURTNEY TRANOS, husband and wife; GEORGE LIMANTZAKIS; RICHARD STEFFENS and NADINE STEFFENS, husband and wife; CHRIS ZAVARELLA and STACEY ZAVARELLA, husband and wife, by and through counsel and complain of defendants, demand a jury trial, and allege as follows:

### **JURISDICTION**

- 1. This Court has subject matter jurisdiction over this action pursuant to the provisions of 28 U.S.C. § 1332.
- 2. This Court has personal jurisdiction over defendants pursuant to Rule 4 of the Oregon Rules of Civil Procedure, in that, at all relevant times described herein, defendants: (a) were registered to do business in the state of Oregon; (b) transacted business in the state of Oregon; (c) contracted to supply goods or services in the state of Oregon; and/or (d) caused injury within the state of Oregon.

# THE PLAINTIFFS

- 3. Plaintiff Scott Warner is a citizen of the state of Oregon. Plaintiff Scott Warner underwent shoulder surgery. He was treated post-operatively with a pain pump designed, developed, manufactured, assembled, packaged, promoted, distributed and/or sold by defendants Stryker Corporation and Stryker Sales Corporation (hereinafter "defendant Stryker"), described below. Upon information and belief, this pain pump was loaded with an anesthetic solution of Marcaine, bupivacaine, and/or Sensorcaine (bupivacaine mixed with epinephrine) created, designed, manufactured, and/or sold by defendants AstraZeneca, Hospira, and/or Abraxis (as defined below).
- 4. Plaintiffs Erin Stout and Russell Stout are citizens of the state of Oregon. Plaintiff Erin Stout underwent shoulder surgery. She was treated post-operatively with a pain pump designed, developed, manufactured, assembled, packaged, promoted, distributed and/or sold by defendant Stryker, described below. Upon information and belief, this pain pump was loaded with an anesthetic solution of Marcaine, bupivacaine, and/or Sensorcaine (bupivacaine mixed with epinephrine) created, designed, manufactured, and/or sold by defendants AstraZeneca, Hospira, and/or Abraxis (as defined below).

- York. Plaintiffs Thomas Bobrick and Barbara Bobrick are citizens of the state of New York. Plaintiff Thomas Bobrick underwent shoulder surgery. He was treated post-operatively with a pain pump designed, developed, manufactured, assembled, packaged, promoted, distributed and/or sold by defendants I-Flow, DJO LLC (f.k.a. DJ Orthopedics, LLC), and/or DJO, Inc., described below. Upon information and belief, this pain pump was loaded with an anesthetic solution of Marcaine, bupivacaine, and/or Sensorcaine (bupivacaine mixed with epinephrine) created, designed, manufactured, and/or sold by defendants AstraZeneca, Hospira, and/or Abraxis (as defined below).
- 6. Plaintiff Brian Cantrell is a citizen of the state of North Carolina. Plaintiff Brian Cantrell underwent shoulder surgery. He was treated post-operatively with a pain pump designed, developed, manufactured, assembled, packaged, promoted, distributed and/or sold by defendant Stryker, described below. Upon information and belief, this pain pump was loaded with an anesthetic solution of Marcaine, bupivacaine, and/or Sensorcaine (bupivacaine mixed with epinephrine) created, designed, manufactured, and/or sold by defendants AstraZeneca, Hospira, and/or Abraxis (as defined below).
- 7. Plaintiff James Evans is a citizen of the state of Arkansas. Plaintiff James Evans underwent shoulder surgery. He was treated post-operatively with a pain pump designed, developed, manufactured, assembled, packaged, promoted, distributed and/or sold by defendant Stryker, described below. Upon information and belief, this pain pump was loaded with an anesthetic solution of Marcaine, bupivacaine, and/or Sensorcaine (bupivacaine mixed with epinephrine) created, designed, manufactured, and/or sold by defendants AstraZeneca, Hospira, and/or Abraxis (as defined below).

- 8. Plaintiffs Weldon Smith and Kellie Smith are citizens of the state of Kansas. Plaintiff Weldon Smith underwent shoulder surgery. On information and belief, he was treated post-operatively with a pain pump designed, developed, manufactured, assembled, packaged, promoted, distributed and/or sold by defendant I-Flow, described below. Upon information and belief, this pain pump was loaded with an anesthetic solution of Marcaine, bupivacaine, and/or Sensorcaine (bupivacaine mixed with epinephrine) created, designed, manufactured, and/or sold by defendants AstraZeneca, Hospira, and/or Abraxis (as defined below).
- 9. Plaintiffs Chris Tranos and Courtney Tranos are citizens of the state of Massachusetts. Plaintiff Chris Tranos underwent shoulder surgery. He was treated post-operatively with a pain pump designed, developed, manufactured, assembled, packaged, promoted, distributed and/or sold by defendant Stryker, described below. Upon information and belief, this pain pump was loaded with an anesthetic solution of Marcaine, bupivacaine, and/or Sensorcaine (bupivacaine mixed with epinephrine) created, designed, manufactured, and/or sold by defendants AstraZeneca, Hospira, and/or Abraxis (as defined below).
- 10. Plaintiff George Limantzakis is a citizen of the state of Utah. Plaintiff George Limantzakis underwent shoulder surgery. He was treated post-operatively with a pain pump designed, developed, manufactured, assembled, packaged, promoted, distributed and/or sold by defendant Stryker, described below. Upon information and belief, this pain pump was loaded with an anesthetic solution of Marcaine, bupivacaine, and/or Sensorcaine (bupivacaine mixed with epinephrine) created, designed, manufactured, and/or sold by defendants AstraZeneca, Hospira, and/or Abraxis (as defined below).
- 11. Plaintiffs Richard Steffens and Nadine Steffens are citizens of the state of Utah.

  Plaintiff Richard Steffens underwent shoulder surgery. He was treated post-operatively with a

pain pump designed, developed, manufactured, assembled, packaged, promoted, distributed and/or sold by defendants Breg, Inc. and/or Orthofix, Inc., described below. Upon information and belief, this pain pump was loaded with an anesthetic solution of Marcaine, bupivacaine, and/or Sensorcaine (bupivacaine mixed with epinephrine) created, designed, manufactured, and/or sold by defendants AstraZeneca, Hospira, and/or Abraxis (as defined below).

- 12. Plaintiffs Chris Zavarella and Stacey Zavarella are citizens of the state of Arizona. Plaintiff Chris Zavarella underwent shoulder surgery. He was treated post-operatively with a pain pump designed, developed, manufactured, assembled, packaged, promoted, distributed and/or sold by defendants Breg, Inc. and/or Orthofix, Inc., described below. Upon information and belief, this pain pump was loaded with an anesthetic solution of Marcaine, bupivacaine, and/or Sensorcaine (bupivacaine mixed with epinephrine) created, designed, manufactured, and/or sold by defendants AstraZeneca, Hospira, and/or Abraxis (as defined below).
- 13. Collectively, plaintiffs Scott Warner, Erin Stout, Thomas Bobrick, Brian Cantrell, James Evans, Weldon Smith, Chris Tranos, George Limantzakis, Richard Steffens, and Chris Zavarella are referred to herein as the "Shoulder Surgery Plaintiffs."
- 14. Collectively, plaintiffs Russell Stout, Barbara Bobrick, Kellie Smith, Courtney Tranos, Nadine Steffens, and Stacey Zavarella are referred to herein as the "Spousal Plaintiffs."

### THE DEFENDANTS

15. Defendants Stryker Corporation and Stryker Sales Corporation are Michigan corporations with their principal places of business in Kalamazoo, Michigan. Stryker Corporation and Stryker Sales Corporation are both registered to do business in the state of Oregon, and have in fact conducted regular and sustained business in Oregon by selling and distributing their products in Oregon, as described below. Collectively, defendants Stryker Corporation and Stryker Sales Corporation are referred to herein as "defendant Stryker."

- 16. Defendant I-Flow Corporation is a Delaware corporation with its principal place of business in Lake Forest, California. Defendant I-Flow has conducted regular and sustained business in Oregon by selling and distributing their products in Oregon, as described below.
- 17. Defendant DJO, LLC (formerly known as DJ Orthopedics, LLC) is a Delaware limited liability company with its principal place of business in Vista, California. Defendant DJO, LLC is registered to do business in the state of Oregon. Collectively, defendant DJO, LLC and defendant DJO, Inc. are referred to herein as "defendant DJO." Defendant DJO has conducted regular and sustained business in Oregon by selling and distributing its products in Oregon, as described below.
- 18. Defendant Breg, Inc. (hereinafter "defendant Breg") is a Delaware corporation with its principal place of business in Vista, California. Defendant Breg was acquired by Defendant Orthofix, Inc. in 2003. Defendant Breg has conducted regular and sustained business in Oregon by selling and distributing its products in Oregon, as described below.
- 19. Defendant Orthofix, Inc. (hereinafter "defendant Orthofix") is a Minnesota corporation with its principal place of business in McKinney, Texas. Defendant Orthofix is registered to do business in the state of Oregon and has conducted regular and sustained business in Oregon by selling and distributing its products in Oregon, as described below.
- 20. Collectively, defendants Stryker, I-Flow, DJO, Breg, and Orthofix are referred to herein as the "Pain Pump Defendants."
- 21. Defendants AstraZeneca, PLC is, on information and belief, a public company organized under the laws of Great Britain, with its principal place of business in Great Britain. On information and belief, defendant AstraZeneca, PLC is neither organized under the law of, nor has its principal place of business in, any state in the United States of America. Defendants

AstraZeneca Pharmaceuticals, LP and AstraZeneca LP, are Delaware limited partnerships with their principal place of business in Delaware. Defendant Zeneca Holdings, Inc. is a Delaware corporation with its principal place of business in Delaware. Defendants AstraZeneca, PLC, AstraZeneca Pharmaceuticals, LP, AstraZeneca, LP, and Zeneca Holdings, Inc. are referred to herein as "defendant AstraZeneca." On information and belief, Defendant AstraZeneca has conducted regular and sustained business in Oregon by selling and distributing its products in Oregon, as described below.

- 22. Defendant Hospira, Inc. (hereinafter "defendant Hospira") is a Delaware corporation with its principal place of business in Lake Forest, Illinois. Defendant Hospira is registered to do business in the state of Oregon and has conducted regular and sustained business in Oregon by selling and distributing its products in Oregon, as described below.
- 23. Defendant Abraxis BioScience, Inc. is a Delaware corporation with its principal place of business in California. Prior to November 13, 2007, defendant Abraxis BioScience, Inc. was named New Abraxis, Inc. On information and belief, defendant Abraxis BioScience, Inc. was also formerly known as American Pharmaceutical Partners, Inc., which was doing business in California as APP Reincorporation Company, Inc.. Also, on information and belief, defendant Abraxis BioScience, Inc. merged with APP Pharmaceuticals, Inc. Abraxis Bioscience, Inc., New Abraxis, Inc., American Pharmaceutical Partners, Inc., APP Reincorporation Company, Inc., and APP Pharmaceuticals, Inc. are hereinafter collectively referred to as "defendant Abraxis."
- 24. Collectively, defendants AstraZeneca, Hospira, and Abraxis are referred to herein as the "Anesthetic Defendants."

# FACTS COMMON TO ALL CLAIMS IN THIS LITIGATION

25. At all relevant times described herein, the Pain Pump Defendants designed, manufactured, assembled, packaged, promoted, marketed, distributed and/or sold pain pumps,

which are medical devices which deliver a continuous and rate-controlled amount of pain medication, via catheter, directly to a surgical site, including the joint space, for post-surgical pain management. The pain medication utilized in these continuous infusion devices included Marcaine (bupivacaine) and Sensorcaine (bupivacaine mixed with epinephrine) designed, manufactured, distributed, and/or sold by the Anesthetic Defendants.

- 26. These pain pumps are all very similar in purpose and function, and are designed to deliver medication at an hourly flow rate or combination of an hourly flow rate and controlled bolus doses. All of these pain pumps, and the anesthetic solutions used therein, were marketed, sold, and distributed as convenient, efficacious, and safe.
- 27. These pain pumps were designed, manufactured, sold, and/or distributed with the intent by the Pain Pump Defendants that they be used over 48 to 72 hours or more. However, the continuous injection of the anesthetic solutions in the volumes, pressures, and length of time achieved by the pain pumps, directly into or in the vicinity of the shoulder joint, can and has caused catastrophic and permanent damage to the cartilage of the shoulder joint or joints of each of the Shoulder Surgery Plaintiffs. As a result, on information and belief, each of the Shoulder Surgery Plaintiffs has suffered from a signature degenerative disease process called post-arthroscopic glenohumeral chondrolysis (PAGCL), resulting in severe and unremitting pain, weakness, loss of strength, decreased range of motion, and other profound injuries.
- 28. As a further and direct result of the use of these pain pumps and anesthetic solutions, the Shoulder Surgery Plaintiffs have been left severely and permanently disabled. They have suffered past and future special (economic) and general (noneconomic) damages, including but not limited to past and future medical and related expenses, past and future lost income and loss of earning capacity, loss of household services, severe and excruciating pain,

mental and emotional distress, intense and unremitting discomfort, permanent injury of their shoulder joints, substantial alterations of lifestyle, loss of enjoyment of life, scarring, and/or other significant damages. In addition, the Spousal Plaintiffs have each provided gratuitous care and have each suffered loss of consortium.

### FIRST CAUSE OF ACTION

(Strict Product Liability Against the Pain Pump Defendants)

- 29. Plaintiffs incorporate by reference the preceding allegations as if fully set forth herein.
- 30. The Pain Pump Defendants designed, manufactured, assembled, labeled, marketed, distributed, and/or sold pain pumps utilized in one or more of the Shoulder Surgery Plaintiffs.
- 31. The pain pumps were defective, unreasonably dangerous, and unsafe in that, among other things:
- (a) The pain pumps were defectively designed and manufactured by the Pain Pump Defendants in that the continuous feed of post-surgical anesthetic solution at the delivery rate utilized by the pain pumps caused permanent injury such as severe chondrolysis, PAGCL and total destruction of cartilage and tissues;
- (b) The Pain Pump Defendants failed to provide adequate warnings and instructions concerning the risks presented by (i) using a higher dosage of pain medication, (ii) inserted into the surgical site, and (iii) for an extended period of time;
- (c) Said instructions and labeling failed to instruct or warn the Shoulder Surgery Plaintiffs, their surgeons, or the United States medical community at large that the safety of these pain pumps and the anesthetic solutions used in them had not been established for use in or near the joint space;

- (d) The instructions and labeling failed to disclose to the Shoulder Surgery Plaintiffs, their surgeons, or the United States medical community at large that continuous injection of commonly-used anesthetics such as those utilized in these pain pumps, with or without epinephrine, for 48 to 72 hours or more, into or near the joint space, is very likely to cause serious and permanent injury to the chondral tissue in that joint;
- (e) The instructions and labeling failed to include a precaution against placing the catheter of these pain pumps in or near the joint space;
- (f) The instructions and labeling failed to provide to the Shoulder Surgery Plaintiffs, their surgeons, or the United States medical community at large adequate instructions and warnings for the safe use of these pain pumps in or near the shoulder joint space;
- Plaintiffs, their surgeons, or the United States medical community at large that the United States Food and Drug Administration (FDA) had specifically considered a request by some or all of the Pain Pump Defendants to permit use of the pain pumps and catheters in the shoulder joint space, and the FDA had specifically rejected this request. Despite this specific rejection by the FDA, the Pain Pump Defendants nonetheless marketed, sold, and/or distributed these pain pumps specifically to be used directly in the shoulder joint space; and
- (h) The defects in these pain pumps made these products unreasonably dangerous.
- 32. The defects in these pain pumps existed when these pain pumps left the Pain Pump Defendants' supervision and control.
- 33. These pain pumps were expected to and did reach the ultimate user without substantial change in the condition in which they were sold and distributed.

- 34. The dangers posed by the defective condition of these pain pumps were not readily recognizable by the ordinary users of these pain pumps.
- 35. The Pain Pump Defendants knew, or reasonably should have known, that users of these pain pumps would not realize the dangerous condition of these pain pumps and their component parts.
- 36. As a direct and proximate result, the Shoulder Surgery Plaintiffs have suffered past and future special (economic) and general (non-economic) damages, including but not limited to past and future medical expenses, past and future lost income, loss of earning capacity, past and future loss of household services, severe and excruciating pain, mental and emotional distress, permanent injury to their joints, substantial alterations of lifestyle, loss of enjoyment of life, scarring, and other significant damages. In addition, the Spousal Plaintiffs have each provided gratuitous care and have each suffered a loss of consortium.

### SECOND CAUSE OF ACTION

(Strict Product Liability Against the Anesthetic Defendants)

- 37. Plaintiffs incorporate by reference the preceding allegations as if fully set forth herein.
- 38. The Anesthetic Defendants designed, manufactured, assembled, labeled, marketed, distributed, and/or sold the anesthetic solutions loaded into one or more of the pain pumps that were utilized in the Shoulder Surgery Plaintiffs.
- 39. The Anesthetic Defendants' anesthetic solutions were defective, unreasonably dangerous, and unsafe in that, among other things:
- (a) The Anesthetic Defendants failed to provide adequate warnings and instructions concerning the risks presented by (i) using a higher dosage of anesthetic solution, (ii) inserted into the surgical site, and (iii) for an extended period of time;

- (b) Said instructions and labeling failed to instruct or warn the Shoulder Surgery Plaintiffs, their surgeons, or the United States medical community at large that the safety of the anesthetic solutions had not been established for use in or near the shoulder joint space;
- (c) The instructions and labeling failed to disclose to the Shoulder Surgery Plaintiffs, their surgeons, or the United States medical community at large that continuous injection of commonly-used anesthetics such as those utilized in the pain pumps, with or without epinephrine, for 48 to 72 hours or more, into or near the shoulder joint space, is very likely to cause serious and permanent injury to the chondral tissue in that joint;
- (d) The instructions and labeling failed to provide to the Shoulder Surgery Plaintiffs, their surgeons, or the United States medical community at large adequate instructions and warnings for the safe use of anesthetic solutions in or near the shoulder joint space; and
- (e) The defects in the anesthetic solutions made those products unreasonably dangerous.
- 40. Upon information and belief, the Anesthetic Defendants were aware of the potentially cytotoxic and destructive effects of the anesthetic solutions that they produced, and were specifically aware that the Pain Pump Defendants were utilizing the Anesthetic Defendants' anesthetic solutions in their pain pumps for infusion into the joint spaces of post-surgical patients, thereby causing injury.
- 41. The defects in the Anesthetic Defendants' anesthetic solutions existed when those solutions left the Anesthetic Defendants' supervision and control.
- 42. Those solutions were expected to and did reach the ultimate user without substantial change in the condition in which they were sold and distributed.

- 43. The dangers posed by the defective condition of those solutions were not readily recognizable by the ordinary users of those solutions.
- 44. The Anesthetic Defendants knew, or reasonably should have known, that users of those solutions would not realize the dangerous condition of those solutions.
- 45. As a direct and proximate result, the Shoulder Surgery Plaintiffs have suffered past and future special (economic) and general (non-economic) damages, including but not limited to past and future medical expenses, past and future lost income, loss of earning capacity, past and future loss of household services, severe and excruciating pain, mental and emotional distress, permanent injury to their joints, substantial alterations of lifestyle, loss of enjoyment of life, scarring, and other significant damages. In addition, the Spousal Plaintiffs have each provided gratuitous care and have each suffered a loss of consortium.

# THIRD CAUSE OF ACTION

(Negligence Against All Defendants)

- 46. Plaintiffs incorporate by reference the preceding allegations as if fully set forth herein.
- 47. At all relevant times, the defendants knew, or in the exercise of reasonable care should have known, that if these pain pumps and associated anesthetic solutions were not properly designed, manufactured, inspected, tested, packaged, labeled, distributed, marketed, and/or if the defendants did not provide proper warnings, they were likely to cause serious bodily injury to the Shoulder Surgery Plaintiffs.
- 48. The defendants failed to exercise reasonable care in the design, manufacture, inspection, testing, packaging, labeling, distribution, and/or marketing of the pain pumps and associated anesthetic solutions and in providing adequate warnings. The defendants' negligence includes, but is not limited to, the following:

- (a) The Pain Pump Defendants negligently designed and/or manufactured these pain pumps and knew or had reason to know that these pain pumps were likely to be dangerous for the use for which they were supplied, i.e., use in or near the joint space;
- (b) The Pain Pump Defendants failed to conduct a proper assessment and analysis of the design and assembly of these pain pumps or their individual parts;
- (c) The Pain Pump Defendants failed to properly test and/or inspect the pain pumps in the environment in which they were to be used to confirm that these pain pumps could be safely used;
- (d) On information and belief, the Anesthetic Defendants failed to properly test and/or inspect their anesthetic solutions in the environment in which they were to be used to confirm that those solutions could be safely used;
- (e) The Pain Pump Defendants failed to exercise reasonable care to inform or warn the Shoulder Surgery Plaintiffs, their surgeons, or the United States medical community at large of the defects in these pain pumps;
- (f) All of the defendants knew, or in the exercise of reasonable care should have known, about the risks that these pain pumps and associated anesthetic solutions presented, and specifically the risk of cartilage and tissue damage that could result from increased dosages of a cytotoxic post-surgical anesthetic solution administered for an extended period of time, and the Pain Pump Defendants nonetheless failed to provide adequate pre- and post-market warnings and instructions to the Shoulder Surgery Plaintiffs, their physicians and other medical providers using these pain pumps;
- (g) All of the defendants knew, or in the exercise of reasonable care should have known, that commonly-used anesthetics likely to be used in these pain pumps, such as

Marcaine, bupivacaine, and Sensorcaine, with or without epinephrine, were harmful to human and animal articular cartilage, and the defendants nonetheless failed to provide adequate pre- and post-market warnings and instructions to the Shoulder Surgery Plaintiffs, their physicians, and other medical providers using their products;

- (h) All of the defendants knew, or in the exercise of reasonable care should have known, that use of pain pumps with these cytotoxic post-surgical anesthetic solutions in a joint space had not been approved and had in fact been specifically rejected by the FDA, and the defendants nonetheless failed to provide adequate pre- and post-market warnings and instructions to plaintiffs, their physicians and other medical providers using their products;
- (i) All of the defendants knew, or in the exercise of reasonable care should have known, that a continuous injection of such cytotoxic post-surgical anesthetic solutions, directly into or near the joint, for 48 to 72 hours or more, had not been adequately tested for safety or effectiveness, and the defendants nonetheless failed to provide adequate pre- and post-market warnings and instructions to the Shoulder Surgery Plaintiffs, their physicians, and other medical providers using their products; and
- (j) All of the defendants knew, or in the exercise of reasonable care should have known, that the risk of PAGCL, or other tissue damage associated with using these pain pumps filled with cytotoxic post-surgical anesthetic solutions directly in or near the joint space, outweighed any possible benefits of such use, and the defendants nonetheless failed to provide adequate pre- and post-market warnings and instructions to the Shoulder Surgery Plaintiffs, their physicians, and other medical providers using their products.
- 49. The defendants' negligence in the design, formulation, manufacture, inspection, failure to test, packaging, labeling, warning, distribution, and marketing of these pain pumps and

post-surgical anesthetic solutions was the direct and proximate causes of plaintiffs' injuries and damages.

50. As a direct and proximate result of the defendants' negligence, the Shoulder Surgery Plaintiffs have suffered past and future special (economic) and general (non-economic) damages, including but not limited to past and future medical expenses, past and future lost income, loss of earning capacity, past and future loss of household services, severe and excruciating pain, mental and emotional distress, permanent injury to their joints, substantial alterations of lifestyle, loss of enjoyment of life, scarring, and other significant damages. In addition, the Spousal Plaintiffs have each provided gratuitous care and have each suffered a loss of consortium.

### FOURTH CAUSE OF ACTION

(Breach of Express Warranty Against the Pain Pump Defendants)

- 51. Plaintiffs incorporate by reference the preceding allegations as if fully set forth herein.
- 52. On information and belief, the Pain Pump Defendants, through their agents and representatives, expressly communicated to the Shoulder Surgery Plaintiffs' surgeons that the Pain Pump was appropriate for use in on near the shoulder joint, and the Shoulder Surgery Plaintiffs' surgeons reasonably relied on that statement in choosing to use pain pumps designed, manufactured, inspected, packaged, labeled, warned, distributed and/or marketed in or near the Shoulder Surgery Plaintiffs' shoulder joints.
- 53. The pain pumps designed, manufactured, inspected, packaged, labeled, distributed and/or marketed by the Pain Pump Defendants did not conform to the Pain Pump Defendants' representations because use of the pain pumps in or near the shoulder joint is unreasonably dangerous.

- 54. The Pain Pump Defendants should have reasonably expected the Shoulder Surgery Plaintiffs to use or be affected by the pain pumps.
- 55. As a direct and proximate result of the failure of the pain pumps designed, manufactured, inspected, packaged, labeled, distributed and/or marketed by the Pain Pump Defendants to conform to the Pain Pump Defendants' representations regarding the propriety of use in or near the shoulder joint, the Shoulder Surgery Plaintiffs have suffered and will suffer severe past and future special (economic) and general (noneconomic) damages, including but not limited to past and future medical expenses, past and future lost income and loss of earning capacity, past and future loss of household services, severe and excruciating pain, mental and emotional distress, permanent injury to their joints, substantial alterations of lifestyle, loss of enjoyment of life, scarring, and other significant damages. In addition, the Spousal Plaintiffs have each provided gratuitous care and have each suffered loss of consortium.

### FIFTH CAUSE OF ACTION

(Breach of Implied Warranty of Merchantability Against All Defendants)

- 56. Plaintiffs incorporate by reference the preceding allegations as if fully set forth herein.
- 57. At the time of their placement into the stream of commerce and at the time of the aforesaid injuries to plaintiffs, these pain pumps and post-surgical anesthetic solutions, together with instructions, warnings, labels, and materials explaining the selection and use thereof, were not fit for the ordinary purposes for which such products are intended and were unmerchantable to users and consumers, including the Shoulder Surgery Plaintiffs.
- 58. As a direct and proximate result of the defendants' breaches of their implied warranties of merchantability, the Shoulder Surgery Plaintiffs have suffered and will continue to suffer severe past and future special (economic) and general (noneconomic) damages, including

but not limited to past and future medical expenses, past and future lost income and loss of earning capacity, past and future loss of household services, severe and excruciating pain, mental and emotional distress, permanent injury to their joints, substantial alterations of lifestyle, loss of enjoyment of life, scarring, and other significant damages. In addition, the Spousal Plaintiffs have each provided gratuitous care and have each suffered loss of consortium.

### SIXTH CAUSE OF ACTION

(Breach of Implied Warranty of Fitness for a Particular Purpose Against All Defendants)

- 59. Plaintiffs incorporate by reference the preceding allegations as if fully set forth herein.
- 60. At the time of their placement into the stream of commerce and at the time of the aforesaid injuries to plaintiffs, these pain pumps and post-surgical anesthetic solutions, together with instructions, labels, warnings and materials explaining the selection, installation and use thereof, were not fit for the particular purpose for which such items were used by the Shoulder Surgery Plaintiffs and their surgeons.
- 61. As a direct and proximate result of the defendants' breaches of their implied warranties of fitness for a particular purpose, the Shoulder Surgery Plaintiffs have suffered and will suffer severe past and future special (economic) and general (noneconomic) damages, including but not limited to past and future medical expenses, past and future lost income and loss of earning capacity, past and future loss of household services, severe and excruciating pain, mental and emotional distress, permanent injury to their joints, substantial alterations of lifestyle, loss of enjoyment of life, scarring, and other significant damages. In addition, the Spousal Plaintiffs have each provided gratuitous care and have each suffered loss of consortium.

### SEVENTH CAUSE OF ACTION

(Loss of Consortium Against All Defendants)

- 62. Plaintiffs incorporate by reference the preceding allegations as if fully set forth herein.
- 63. As a direct and foreseeable result of the injuries to their spouses, as set forth above, the Spousal Plaintiffs have each suffered loss of the society, comfort, support, and services of their spouses, all to their damage.

# **DAMAGES**

- 64. Plaintiffs incorporate by reference the preceding allegations as if fully set forth herein.
- 65. As a result of the acts and omissions of defendants set forth generally above, and other and further acts and omissions of a similar nature, the Shoulder Surgery Plaintiffs have each suffered and will suffer the following damages:
  - (a) Past expenses for medical, surgical, nursing, therapy, and equipment;
  - (b) Future medical, surgical, nursing, therapy, and equipment expenses;
  - (c) Past and future lost wages and impairment of earning capacity;
  - (d) Past and future loss of household services;
  - (e) Past and future care gratuitously rendered;
- (f) General damages for severe and excruciating pain, suffering, mental and emotional distress, permanent disability, substantial alterations of lifestyle, loss of enjoyment of life, scarring, and other significant damages; and
- (g) Plaintiffs' costs of this action, together with interest on special and general damages from the date of occurrence at the legal rate until paid, interest on any judgment awarded herein at the legal rate until paid, and other and further relief as the Court deems equitable and just.

### **PUNITIVE DAMAGES**

- 66. Plaintiffs incorporate by reference the preceding allegations as if fully set forth herein.
- 67. In acting or in failing to act in all of the particulars set forth above, the defendants have acted with malice or have shown a reckless and outrageous indifference to a highly unreasonable risk of harm, and have acted with a conscious indifference to the health, safety, and welfare of others.
  - 68. As such, the defendants are liable to plaintiffs for punitive or exemplary damages.

\* \* \* \* \* \*

#### WHEREFORE

- 1. The Shoulder Surgery Plaintiffs pray for judgment in their Causes of Action against defendants as follows:
- (a) Past expenses for medical, surgical, nursing, and rehabilitative care, therapy, and equipment;
- (b) Future medical, surgical, nursing, and rehabilitative care, therapy, and equipment;
  - (c) Past and future lost wages and impairment of earning capacity;
  - (d) Past and future loss of household services;
  - (e) Past and future care gratuitously rendered; and
- (f) General damages for severe and excruciating pain, suffering, mental and emotional distress, permanent disability, substantial alterations of lifestyle, loss of enjoyment of life, scarring, and other significant damages.

- 2. The Spousal Plaintiffs pray for judgment in their Causes of Action against defendants for loss of the society, comfort, support and services of their spouses and partners, all to their damage; and
- 3. All plaintiffs pray for judgment in their Causes of Action against defendants as follows:
  - (a) Punitive or exemplary damages; and
- (b) Interest on special and general damages at the legal rate until paid, interest on any judgment awarded herein at the legal rate until paid, and such other and further relief as the Court deems equitable and just.

# **DEMAND FOR JURY TRIAL**

Plaintiffs request that this case be tried by a jury.

DATED this day of November, 2008.

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**Attorneys for Plaintiffs**